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| Department of Health & Human Services  National Institute of Mental Health | | **MEG Core Facility** | |
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| Filing aVariance / Process Improvement Report | | | |
| **What Is a Variance?**  A *Variance* is any event, occurrence or deviation from normal operations, policies, procedures and practices involving any users, subjects/patients and /or equipment.  The Variance process will be used to track, evaluate / assess, and manage equipment malfunctions and failures and prevent adverse events, near-misses, close calls, hazardous conditions, injuries and sentinel events.  The essential objective of the variance reporting process is to determine the factors contributing to the occurrence in order to implement, fix, and maintain equipment and also put in place practices and systems to prevent recurrence of problems or irregularities. |  | | **What is**  **Process Improvement (QA/QI)?**  *Process Improvement* (QI / QA) is the process whereby the MEG Lab measures, monitors and evaluates the quality of services provided in order to pursue opportunities for improvement. The focus of process improvement is proactive rather than reactive.  In addition, the Quality Assurance /Quality Improvement process serves as an instrument whereby recommendations for change, efficiency or innovation can be initiated by subjects / patients, users or staff as a part of the ongoing quality assurance/process improvement program. |
| **Why Should I File A Variance Report?**  ***You should file a Variance Report so that we can resolve any problem you may discover in a timely manner.***  *Variance Reporting* is part of the overall MEG Quality Assurance /Quality Improvement Plan. You should file a Variance to report any departure from normal policy and procedure, equipment malfunction/failure, adverse events, near-misses, close calls, or hazardous conditions involving staff, users, subjects/patients and/or equipment so that the MEG staff can effectively identify, evaluate and resolve any problems or potential problems in a timely manner no matter how big or small. |  | | **Why Should I File a QA / QI Report?**  ***You should file a QA/QI Report so that we can better serve you.***  The *QA/QI Process* will give MEG patients, users and staff a voice- a means to make suggestions and recommendations for improvements so that we can continuously strive to become better and better.  These suggestions can pertain to any aspect of the operations of the MEG Core Facility. |
| |  | | --- | | *The Variance / QA/QI reporting process is designed to integrate both proactive and reactive mechanisms of*  *risk management and the safety program while serving as a vehicle for quality improvement / process*  *improvement initiatives.* | | | | |

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| MEG Core Facility **Filling Out a Variance / QA – QI Report** |
| |  |  | | --- | --- | | 1. **Variance Reporting**  |  | | --- | | **To be completed by the witness** |   The Principal Investigator (PI) will be responsible for meeting all Clinical Center and MEG Core Facility requirements. The PI will be responsible for any medical complications or incidents involving a patient / subject or the experimenter conducting the study. In addition, he/she will be responsible for reporting:   * all variances via the MEG Variance Reporting System, * any adverse events via the Clinical Center’s Occurrence Reporting System, * any unsafe conditions and safety related incidents to the Clinical Center’s Safety Committee, and * all equipment / medical device malfunctions, with and without injury to the manufacturer and/or the Food & Drug Administration (FDA).   *\*Refer to Adverse Event / Safety / Medical Device Reporting*, *Policy & Procedure 10.92.*  In the absence of the PI, the person conducting the study / observing the variance will be responsible for completing a Variance Report and notifying MEG Core staff of all incidents or safety related issues.  Anyone witnessing an occurrence or variation in normal operations, policies, procedures, and practices involving either staff, users, subjects, patients and / or equipment must fill out a Variance Report within 24 hours. Fill out all sections (A – N).   * 1. **Defective / Faulty or Damaged Equipment** * Discontinue use of any defective / faulty / malfunctioning or damaged equipment. * Take the equipment out of service immediately. Place an **“Out of Service / Do not Use”** sticker on the equipment (a supply of stickers will be kept on the Variance Clip Board). This equipment must not be used until it has been tested and / or repaired. * Write a Variance Report describing the sequence of events, include the date, time taken out of service, the name and phone number of the person making the report. | |

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| **cont.:**   * 1. **Electronics Failure** * If the electronics fail consult the Troubleshooting Guide located on the Variance Report Clip Board and follow the instructions. * If the problem persists, contact MEG Core staff for assistance.   1. **Acquisition Failure** * If acquisition fails to launch at any time follow the instruction as outlined in the Troubleshooting Guide located on the Variance Report Clip Board. * If necessary, contact MEG Core staff for additional assistance. * Complete a Variance Report.   1. **Injury** * Attend to the subject; follow the appropriate emergency policies and procedure. * Notify the Director of the MEG Core Facility as soon as possible after the occurrence. * A Variance Report must be filled out if a subject / patient, user, or staff member is involved in an incident with injuries while in the MEG Core Facility.   1. **Policy, Procedure or Practice Variance** * Report using the Variance Form. * Write a description of the situation as it occurred; give as much detail as possible.  1. **QI / QA Reporting**  |  | | --- | | **Can be submitted anonymously by any individual** |   **a. QI / QA Recommendations**   * Check the appropriate box to make recommendations, provide suggestions or give general feedback to the MEG staff. * Submitter may remain anonymous if so desired; however, if information or feedback is desired contact information must be provided. Feedback will be provided in a timely manner. * At a minimum Section 1 A, B, and D should be completed. |

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| |  | | --- | | **MEG Staff** |  * Outcome – the results of the investigation; the equipment/ incident will be investigated by MEG staff and the outcome of the investigation will be documented.      * Recommendations – possible solutions will be evaluated. * Process Improvement – measures will be implemented to prevent the re-occurrence. Users will be informed of the resolution.   11/08; Rev. 6/18 |